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10/593,682	08/18/2008	Yukimitsu Suda	TOS-170-USA-PCT	2820
27955	7590	02/10/2012	EXAMINER	
TOWNSEND & BANTA Suite 900, South Building 601 Pennsylvania Ave., N.W. Washington, DC 20004			JONES JR., ROBERT STOCKTON	
			ART UNIT	PAPER NUMBER
			1762	
			NOTIFICATION DATE	DELIVERY MODE
			02/10/2012	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/593,682	<b>Applicant(s)</b> SUDA ET AL.	
	<b>Examiner</b> ROBERT JONES JR.	<b>Art Unit</b> 1762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1 and 2 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 October 2011 has been entered.

### ***Claim Interpretation***

2. Claims 1 and 2 have been amended to recite the limitation "said carboxymethyl phosphorylcholine obtained by the oxidative cleavage of 1- $\alpha$ -glycerophosphorylcholine using periodate and ruthenium trichloride in a water/acetonitrile mixed solvent". This represents a product-by-process limitation.

3. When a product recited in product-by-process format reasonably appears to be the same as or obvious from a product of the prior art, the burden is on applicant to show that the prior art product is in fact different from the claimed product, even though the products may be made by different processes. Cf. *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). This principle applies even in the context of a process claim that

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recites a step of using a product that is defined by the method by which it is produced.

Cf. *In re Hirao*, 535 F.2d 67, 69 (CCPA 1976).

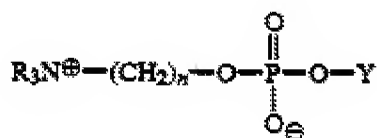
4. Absent evidence of criticality regarding the presently claimed process, it is determined that a process according to Claims 1 and/or 2 which employs a carboxymethyl phosphorylcholine according to Formula 2 will read on the claim(s), regardless of the method by which said carboxymethyl phosphorylcholine is obtained.

### ***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowers in view of Matsuda.

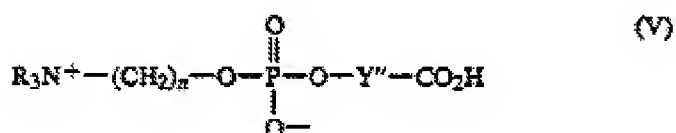
7. Bowers teaches a process for treating synthetic polymers to improve their ocular, hemo, and biocompatibility. Said polymers are widely employed in hard, soft, and intraocular lenses (col. 1, lines 6-12). Bowers discloses that such treatment results in reduced protein and cell deposition at polymer surfaces (col. 1, lines 26-28). The process comprises the steps of (a) where appropriate, activating the surface to be treated; and (b) treating the surface with a compound of general formula (I) (col. 1, lines 29-40):



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Step (a) may be omitted where the polymer surface has sufficient free hydroxyl groups for reaction with compounds of formula (I) (col. 4, lines 43-46).

8. Suitable compounds according to formula (I) include carboxylic acid derivatives of phosphorylcholine (col. 9, lines 19-30):



9. Y'' is a group such as  $-(\text{CH}_2)_p-$ , wherein p is preferably 1-6 (col. 9, lines 28-30; col. 1, lines 52-53). Thus, Bowers discloses a process which results in a contact lens material having hydroxyl groups which have been functionalized by a compound identical to the claimed formula (2) wherein  $n=1-6$ . The species of carboxymethyl phosphorylcholine according to Chemical Formula 2 wherein  $n=1$  is included in the genus taught by Bowers, wherein  $n=1$ .

10. Bowers' treatment process is preferably conducted in aqueous medium using a sodium bicarbonate buffer (col. 5, lines 33-38). Therefore, Bowers does not teach that the claimed method is carried out in an organic solvent.

11. In the same field of endeavor, Matsuda teaches the formation of contact lenses (Abstract). Matsuda's method involves formation of an ester bond. The ester bonding reaction can be effected by allowing a carboxylic acid derivative to react with a hydroxyl group either in an organic solvent such as DMF, DMSO, HMPA, or THF; or in an aqueous solvent or buffer solution (col. 4, lines 33-51). Thus, Matsuda discloses that when forming contact lens materials, esterification reactions are equally successful when carried out in aqueous or organic solvents.

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12. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bowers in view of Matsuda to substitute an organic solvent for an aqueous solution, as these conditions are taught by Matsuda as being equivalents suitable for carrying out esterification reactions with contact lens materials.

13. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowers in view of Matsuda as applied to claim 1 above, and further in view of Valint, Jr.

14. Regarding Claim 2, Bowers in view of Matsuda remains as applied to Claim 1 above. Bowers teaches that for synthetic polymers which do not have adequate free surface hydroxyl groups, it is necessary to activate the surface before treatment with the compounds of formula (I) (col. 4, lines 55-60). Bowers does not teach a specific method for achieving hydroxylation of a polymer surface.

15. In the same field of endeavor, Valint teaches a method for the surface treatment of silicone hydrogel contact lenses. In one embodiment, the surface of a lens is coated by subjecting said surface to: a plasma oxidation reaction, followed by a plasma polymerization reaction in the presence of a diolefin. Finally, the resulting carbon layer is rendered hydrophilic by a further plasma oxidation reaction (Abstract). In addition to rendering the surface hydrophilic, Valint's process results in a coating which is resistant to delamination and/or cracking (col. 3, lines 66-67).

16. It would have been obvious to modify Bowers in view of Matsuda as applied above, and further in view of Valint to introduce hydroxyl groups as per Bowers' step (a) through plasma treatment as taught by Valiant. This method is demonstrated as being

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successful in treatment of contact lens materials, and results in resistance to delamination and cracking.

### ***Response to Arguments***

17. Applicant's arguments filed 8 October 2011 have been fully considered but they are not persuasive.

18. The Applicant argues that Bowers teaches away from the claimed process because the reference employs an aqueous solution during aftertreatment. The Applicant argues that one of ordinary skill in the art would interpret this as a suggestion that such a process would not proceed successfully in an organic solvent.

19. In the entirety of the reference to Bowers et al, there is no express teaching away from the use of an organic solvent. It is true that the reference teaches that preferred aftertreatment conditions make use of a buffered aqueous solvent. However, one skilled in the art would not assume from this teaching that the reaction would not proceed in an organic solvent. If anything other than a preferred set of conditions can be inferred from this teaching, one skilled in the art would suspect that the success of the reaction was dependent upon the polarity of the solvent. Water is a highly polar solvent; one skilled in the art would conclude that the reaction would proceed successfully in an organic solvent, so long as the solvent possessed the appropriate degree of polarity. As stated above, Matsuda teaches organic solvent such as DMF, DMSO, HMPA, or THF; or aqueous solvents or buffer solutions as being suitable for use

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during esterification reactions when after-treating contact lens material. One skilled in the art will immediately recognize that the solvents disclosed by Matsuda, particularly DMF, DMSO, and HMPA, are highly polar organic solvents. Based on the high polarity of the solvents disclosed by Matsuda and the fact that they are taught as being interchangeable with aqueous solvents or buffer solutions, one of ordinary skill in the art would have no reason to suspect that Bowers' esterification reaction would not proceed successfully when carrying out the proposed modification.

20. The Applicant argues that Bowers fails to teach the product-by-process limitation now present in Claims 1 and 2 which is associated with carboxyl phosphorylcholine. The Applicant argues that this process proceeds easily at room temperature and requires only a catalytic amount of the ruthenium compound.

21. As stated above, when a product recited in product-by-process format reasonably appears to be the same as or obvious from a product of the prior art, the burden is on applicant to show that the prior art product is in fact different from the claimed product, even though the products may be made by different processes. Cf. *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). This principle applies even in the context of a process claim that recites a step of using a product that is defined by the method by which it is produced. Cf. *In re Hirao*, 535 F.2d 67, 69 (CCPA 1976). In the present case, the Applicant has not demonstrated that the product resulting from the process in question is chemically different from the product taught by Bowers. While the process in question may be more efficient or economical, it nevertheless results in a product which is identical in every way to that disclosed by Bowers.



22. The Applicant argues that Matsuda fails to teach esterification of the carboxymethyl phosphorylcholine as claimed, and fails to teach the product-by-process limitation associated with that compound.

23. While Matsuda does not disclose all the features of the present claimed invention, it is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention. If the secondary reference contained all the features of the present claimed invention, it would be identical to the present claimed invention, and there would be no need for secondary references.

24. The Applicant argues that the test results shown in Figure 1 clearly show the unexpectedly low protein adsorption by contact lenses formed according to the presently claimed method, versus contact lenses treated according to conventional methods. The Applicant argues that the experimental test results presented in Figure 1 are explained in sufficient detail to enable one skilled in the art to determine their significance. The Applicant points to page 26, [0044] of the specification as showing what is being measured by the y axis of Figure 1. According to the Applicant, the statements "the protein level in the solution portion was quantified with the BCA method" and "the protein adsorption level was determined as the reduction in the

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proteins in the solution portion” make clear to the reader that the y-axis denotes adsorbed protein in mg in the contact lens.

25. Contrary to the Applicant’s assertion, there is absolutely no indication anywhere within the specification of what the BCA method is, or that it necessarily and invariably produces results indicated by adsorbed protein in mg.

26. The Applicant argues that although Bowers achieves a 96% reduction in protein adsorption, the present inventors could not replicate such results. The conclusion is that Bowers’ Example 5 is inoperable. The Applicant further argues that the Examiner is not warranted in relying upon Bowers’ Example 5 to show a contact lens exhibiting a high degree of protein adsorption reduction because Bowers discloses results for only one composition.

27. The Applicant has provided no evidence that Bowers’ disclosure is inoperative; the arguments rely on mere argument and conclusory statements without any experimental results. Additionally, it is noted that while the Applicant seeks to discredit Bowers’ results for only employing one composition, the results upon which the Applicant relies (Examples 1 and 2) employ only one composition.

28. The Applicant argues that the experiment disclosed in the instant specification was conducted in a protein solution of much higher concentration than Bowers (mg order vs  $\mu$ g order, respectively), and therefore the results of Experiments 1 and 2 are more significant than the results observed by Bowers.

29. Regardless of the concentration in the instant Examples, the fact remains that reduced adsorption of protein on a contact lens surface following treatment with a

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phosphorylcholine derivative is not an unexpected phenomenon. Bowers states that "[t]he coating produced is permanent and results in reduced protein and cell deposition at polymer surfaces" (col. 1, lines 26-28). Bowers' lenses are not treated in a solution containing protein on a microgram scale; rather, they are immersed in a "known volume of a protein solution comprising a known concentration" of protein (col. 17, lines 43-46). The amount of protein adsorbed onto the treated lenses is quantified in micrograms. The treatment taught by Bowers results in a 96% reduction in protein adsorption from a protein solution of unknown concentration. Regardless, the reference clearly leads one of skill in the art to expect the phenomenon of reduced protein adsorption observed in the instant Examples. The concentration of the Applicant's protein solution does not change the fact that the observed results would be expected and predictable based on the prior art.

30. The Applicant argues that Bowers does not describe a synthesis method for a phosphorylcholine derivative, and therefore cannot be called a disclosure of an invention. The Applicant argues that if the compound were to be synthesized based on ordinary organic chemistry commonsense, the method would be very cumbersome and the yield would be low.

31. The reference to Bowers need not disclose a synthetic method for arriving at the phosphorylcholine derivative in question to demonstrate possession and use of the compound. The fact remains that Bowers produces experimental results which employ the compound in question, thus indicating possession of said compound in the prior art. Regardless, the fact remains that Bowers' Example 2 provides a synthetic method

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which would allow one of ordinary skill in the art to obtain the phosphorylcholine derivative. The Applicant's arguments that such a method would be cumbersome and low-yielding do not change the fact that such methods exist in the cited prior art and would allow one to obtain the compound employed in the claimed method, and to employ it in the method taught by Bowers.

32. The Applicant argues again that Bowers' example 5 could not be duplicated and cannot be trusted by one of ordinary skill in the art of organic synthesis. The conclusion is that Bowers is not reliable and should not thus be cited as the primary reference to reject the present invention.

33. Again, the Applicant has provided no evidence that Bowers' disclosure is inoperative; the allegation of unreliability rely on mere argument and conclusory statements without any experimental results. Outside of the Applicant's assertions, there exists no reason why one of ordinary skill in the art would doubt the accuracy or veracity of the results presented within Bowers.

34. The Applicant argues that Valint does not disclose after-treatment of a contact lens material with the phosphorylcholine group-containing chemical compound as required by Claim 2, and does not disclose or suggest the synthetic method of the phosphorylcholine group-containing chemical compound.

35. While Valint does not disclose all the features of the present claimed invention, it is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ

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871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention. If the secondary reference contained all the features of the present claimed invention, it would be identical to the present claimed invention, and there would be no need for secondary references.

36. Additionally, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

### ***Conclusion***

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT JONES JR. whose telephone number is (571)270-7733. The examiner can normally be reached on Monday - Thursday, 9 AM - 5 PM.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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39. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROBERT JONES/  
Examiner, Art Unit 1762